

## FACILITATING DRAINAGE

Cross-Reference to Related Applications

This claims priority to and the benefit of each of the following two provisional U.S. patent applications: serial number 60/180,131 filed on February 3, 2000, and serial number 60/188,002 filed on March 9, 2000.

Technical Field

This invention relates to facilitating drainage and, more particularly, to facilitating fluid drainage from the bladder and through the urethra of a patient.

Background Information

The prostate is a gland in the male urinary system located directly below the bladder and around the urethra. In some men, especially men over fifty years of age, the prostate can become swollen or enlarged due to disease or infection. The enlarged prostate constricts the urethra causing discomfort and/or bladder outlet obstruction.

Insult > ~~One of the known procedures for treating an enlarged prostate is thermal prostatic therapy. During thermal prostatic therapy, the prostate is heated above body temperature to remove the diseased tissue, whereby returning the prostate to normal size. Immediately after treatment, however, the prostate is still swollen or enlarged due to the therapeutic trauma induced by the procedure. It may take several weeks before the treated prostate recovers and no longer inhibits bladder drainage.~~

09733752-120800

### Summary of the Invention

The invention involves providing drainage of fluid from the bladder of a patient. Systems and methods of the invention typically are used after the patient has undergone prostate treatment such as thermal therapy. Systems and methods according to the invention involve converting in situ a urinary drainage catheter into an indwelling device. The device maintains the prostatic section of the urethra open and able to pass fluid while also allowing normal operation of the patient's external sphincter such that the patient has full and normal control over the retention and discharge of urine from the bladder even with the device in place within the prostatic section of the urethra.

In general, in one aspect, the invention relates to a prostatic stent. The prostatic stent comprises a body member and a retaining member. The body member includes a distal terminating end, a proximal end portion, and a lumen extending within the body member to allow fluid to drain through the body member. The directional terms proximal and distal require a point of reference. In this application, the point of reference in determining direction is in the perspective of the patient. Therefore, the term proximal will always refer to a direction that points into the patient's body, whereas distal will always refer to a direction that points out of the patient's body. The body member is sized for placement substantially within the prostatic section of the urethra. The distal terminating end is positioned proximal of an external sphincter so as to allow normal operation of the external sphincter. The retaining member extends from the proximal end portion of the body member. The retaining member is collapsible into a first state to allow the passage of the prostatic stent into the urethra in the first instance. The retaining member also is expandable into a second state when located in the bladder to hold the body member in place substantially within the prostatic section of the urethra.

Embodiments of this aspect of the invention can include the following features. The retaining member of the prostatic stent can be tapered to provide comfort to the patient during insertion of the stent into the patient's urethra. The retaining member also can comprise two or more retaining arms, and the retaining arms can be biased in the second state. Prior to and during insertion of the prostatic stent into the patient's urethra, the retaining member is in the first state. The retaining member returns to substantially the second state once in the patient's bladder and thereby acts as an anchor to keep the body member of the prostatic stent substantially within the

09733752-120300

prostatic section of the urethra. The body member of the prostatic stent can include one or more side openings to allow fluid to drain from the prostatic section of the urethra into the lumen. To help prevent migration of the prostatic stent, the body member also can have one or more protrusions. The protrusions are designed to engage the wall of the prostatic urethra and thereby provide a source of friction that limits the motion of the prostatic stent within the urethra. The body member also can include a suture attached to the distal terminating end. The suture should be long enough to extend from the body member to the patient's meatus. The prostatic stent can be removed easily from the patient's body by pulling on the suture. The end of the suture can be connected to a ball, ring, coil, or other structure that either extends out of the body entirely or is located within the meatus. The point of the ball, ring, coil or other structure at the end of the suture is to facilitate location of the end of the suture and then removal of the stent by the patient himself or by a medical professional, simply by pulling on the located suture.

In another aspect, the invention relates to a prostatic stent-catheter system for draining fluid from the bladder, through the prostatic urethra, and out of the patient's body. The prostatic stent-catheter comprises a stent and a connecting segment. The stent includes a body member comprising a distal terminating end, a proximal end portion, and a lumen extending within the body member. The body member is sized for placement substantially within the prostatic section of the urethra with the distal terminating end located proximal of the external sphincter to allow normal operation of the external sphincter. The connecting segment comprises an elongated body member including a distal end, a proximal end, and a lumen. The proximal end of the connecting segment is releasably coupled to the distal terminating end of the stent. The prostatic stent-catheter system has at least two modes of operation after being inserted into the patient's urethra. In a first mode, the stent and connecting segment are coupled together, and drainage of fluid from the bladder occurs continuously. In a second mode, the connecting segment is decoupled from the stent in situ, and the connecting segment then is removed from the patient's urethra. After the connecting segment is removed from the patient's body, the patient's external sphincter contracts and is allowed to function normally to allow the patient have full control over voiding of urine.

Embodiments of this aspect of the invention can include the following features. The stent portion of the prostatic stent-catheter can further include a retaining member extending

09733752.120800

proximally away from the body member. When the stent-catheter system is properly positioned, the retaining member will be located in the patient's bladder. In one embodiment the retaining member comprises a proximal curved tip that acts as an anchor within the bladder opening to prevent the distal migration of the stent. In another embodiment, the retaining member includes at least two retaining arms biased in an expanded state. The retaining arms are collapsible and are collapsed prior and during the insertion of the prostatic stent-catheter into the patient's urethra. The retaining arms in the present embodiment return to the expanded state once located in the patient's bladder and thereby act as an anchor to prevent stent migration. The contraction and the expansion of the retaining arms can be controlled through a pushing device while the prostatic stent-catheter is within the patient's body. The stent portion of the prostatic stent-catheter system can further include a body member comprising of a large pore mesh. The large pore mesh can be fabricated from any biocompatible, self-expanding material such as a nickel-titanium based alloy. The body member including the large pore mesh frictionally engages the patient's prostate, whereby anchoring the stent to prevent migration.

In general, in still another aspect, the invention relates to a method of placing a prostatic stent-catheter system within the urethra. The prostatic stent-catheter system, which includes a stent and a connecting segment releasably coupled to one another, is inserted into the urethra of the patient. A medical professional such as a physician advances the prostatic stent-catheter system through the urethra until at least a portion of the stent is positioned substantially within the prostatic section of the urethra. When properly positioned, at least a portion of the stent will reside within the prostatic section of the urethra, while the connecting segment will extend through the external sphincter, through the rest of the urethra, and outside of the patient's body. The physician will know that the prostatic stent-catheter system is properly positioned when urine or other bodily fluid is observed draining through the distal end of the connecting segment. Bodily fluids such as urine and blood draining through the prostatic stent-catheter system are monitored. If the procedure is being done after treatment (e.g., surgery) on the prostate, the medical professional must determine when the patient's prostate has recovered or is recovering sufficiently from the treatment, and then the professional decouples the connecting segment from the stent and withdraws the connecting segment entirely from the patient's body. The stent thus remains within the prostatic section of the urethra to prevent bladder outlet obstruction and to

09733752-120600

keep the prostatic section of the urethra open and passing fluid(s) from the bladder while allowing normal operation of the patient's external sphincter. Once the prostate has fully recovered and poses no risk of obstructing fluid drainage, the stent can be removed. Removal of the indwelling stent can be accomplished by pulling on a suture attached to the stent. The suture typically is left extending from the urethra outside of the patient's body, or it can be left just within the meatus and therefore easily located by the patient himself or a medical professional such as a doctor or nurse.

The foregoing and other objects, aspects, features, and advantages of the invention will become more apparent from the following description and from the claims.

09733752-120800

### Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

FIG. 1 is a schematic view of a prostatic stent-catheter system according to one embodiment of the present invention.

FIG. 2 is an exploded view of the prostatic stent-catheter system shown in FIG. 1.

FIG. 3 is a schematic view of one embodiment of a prostatic stent.

FIG. 4 is a schematic view of another embodiment of a prostatic stent.

FIG. 5 is a schematic view of another embodiment of a prostatic stent.

FIG. 6 is a schematic view of another embodiment of a prostatic stent.

FIG. 7 is a schematic view of one embodiment of a pushing device of a prostatic stent-catheter system according to the invention.

FIG. 8 is a schematic view of another embodiment of a pushing device.

FIG. 9 is an enlarged view of the proximal end of one embodiment of a pushing device.

FIG. 10 is an enlarged plan view of a prostatic stent.

FIG. 11 is a side view of the prostatic stent shown in FIG. 10.

FIG. 12 is a cross-sectional view of the prostatic stent taken along the lines 8-8 in FIG. 10.

FIG. 13 is a schematic view of both a handle mechanism in a first position and a corresponding collapsed prostatic stent configuration with an engaged pushing device.

FIG. 14 is a schematic view of both a handle mechanism in a second position and a corresponding expanded prostatic stent configuration with an engaged pushing device.

FIG. 15 is a schematic view of both a handle mechanism in a third position and a corresponding expanded prostatic stent configuration with a disengaged pushing device.

FIG. 16 is a plan view of another embodiment of a prostatic stent-catheter system, in an insertion configuration.

FIG. 17 is an enlarged plan view of the prostatic stent shown in FIG. 16.

FIG. 18 is the prostatic stent-catheter system of FIG. 16 in a release configuration.

09733752-120800

FIG. 21 is a schematic view of a male urinary system and the prostatic stent-catheter system of FIG. 20 prior to insertion.

FIG. 23 is a schematic view illustrating proper placement of the prostatic stent-catheter system of FIG. 19.

FIG. 25 is a schematic view illustrating connecting segment removal from the male urinary system.

FIG. 27 is an enlarged schematic view of another embodiment of a retaining device.

FIG. 28 is an enlarged schematic view of another embodiment of a retaining device.

### Description

The invention generally relates to relieving bladder outlet obstruction. After prostate treatment, a patient can experience urinary retention. The invention generally involves treating urinary retention, especially male urinary retention, while still allowing normal operation of the patient's external sphincter (and thus allowing normal voiding of the bladder) even with a stent located temporarily within the prostatic section of the patient's urethra.

Inc 3<sup>2</sup> ~~After a medical procedure to treat an obstructed prostate, such as thermal prostate therapy, a patient may experience prostate bleeding while the recently treated prostate recovers. Another consequence of such medical procedures is bladder outlet obstruction which results from the still slightly enlarged and recovering prostate. After the procedure, the medical professional (e.g., a physician) that performed the procedure or some other medical professional will monitor the amount of urine and prostate bleeding, and attempt to provide the patient with an open urinary passageway. In order to monitor continuously the bodily fluids from the patient's bladder and prostate, the medical professional(s) attending to the patient need to prevent the patient's external sphincter from closing to allow constant and uninterrupted drainage of those bodily fluids. In general, the attending professional(s) only need(s) to monitor the flow of blood and urine from the patient's urinary system for a few hours. It may, however, take several weeks for the patient's prostate to recover. One of the objects of the present invention is to provide devices, systems, and methods which will maintain an open passageway throughout the patient's entire urinary system such that constant drainage can be realized for some period of time just after treatment of the prostate, and which also can thereafter provide an open urinary passageway from the bladder through the prostatic section of the urethra while simultaneously allowing normal operation of the patient's external sphincter such that the patient has full and normal control over bladder voiding.~~

Referring to FIGS. 1 and 2, a prostatic stent-catheter system 1 of the invention comprises a prostatic stent 3 and a connecting segment 6. The prostatic stent 3 includes a body member 5 made of one or more biocompatible materials such as silicone, nylon, polyglycolic acid, or stainless steel, and sized to fit substantially within the prostatic section of the urethra. The body

00733752-120600



member 5 has a proximal end 7, a distal terminating end 4, and a lumen extending from the proximal end 7 to the distal terminating end 4 to allow fluid drainage through the body member 5. As previously mentioned in this application, the term proximal refers to a direction that points into the patient's body and the term distal refers to a direction that points out of the patient's body. The body member 5 may be reinforced with a wire mesh to increase the tensile strength of the prostatic stent 3 whereby decreasing the possibility of the lumen collapsing. The prostatic stent 3 as illustrated in FIGS. 1 and 2 further comprises a retaining member 8. The retaining member 8 is also made from one or more biocompatible materials. In the disclosed embodiment, the retaining member 8 has at least two retaining arms 13a and 13b. Other retaining member 8 embodiments are possible, so long as these embodiments anchor the body member 5 within the prostatic section of the urethra, and do not inhibit fluid drainage from the bladder. Examples of some other retaining members are given in FIGS. 3-6. Other further possible embodiments of retaining member shapes include umbrella shaped prongs and a pigtail curl. All retaining member embodiments must be either collapsible or able to be straighten for insertion ease. Similarly, a retaining member is not required if a prostatic stent includes another means to prevent migration of the prostatic stent from the prostatic section of the urethra (for example, a body member that frictionally engages the patient's prostate). The retaining member 8, as shown as in the embodiment of the device in FIGS. 1-2, also includes a proximal tip 2. Within the proximal tip 2, there is a lumen extending from a base proximal tip opening 9 to a proximal tip opening 11. The retaining member 8 is collapsible and has at least two distinct states. In a first state, the retaining member 8 is collapsed to allow for insertion ease. In a second state, the retaining member 8 is expanded to secure the prostatic stent 3 from significant migration after the prostatic stent 3 has been properly positioned. The prostatic stent 3 is properly positioned within a male patient's urinary system, when the retaining member 8 is located within the patient's bladder and the body member 5 is located substantially within the prostatic section of the urethra with the distal terminating end 4 being located proximal to the patient's external sphincter. The connecting segment 6 of the prostatic stent-catheter system 1 comprises an elongated body member 29 having a proximal end 28 and a distal end 30. A lumen extends from the proximal end 28 to the distal end 30 for fluid drainage. At the distal end 30 of the connecting segment 6 there is at least one side opening 26 for fluid drainage.

09733752-120800

During insertion of the prostatic stent-catheter system 1, the proximal end 28 of the connecting segment 6 is releasably coupled to the distal terminating end 4 of the prostatic stent 3. The coupling of the prostatic stent 3 with the connecting segment 6 creates a single lumen extending from the proximal end 7 of the body member 5 to the distal end 30 of the connecting segment 6. To couple the prostatic stent 3 to the connecting segment 6 a guide 40 is used. The guide 40 is an open ended tubular body member having a slightly smaller diameter than both the connecting segment 6 and the body member 5. The guide 40 is fastened to the proximal end 28 of the connecting segment 6 such that a portion of the guide 40 is within the lumen of the connecting segment 6 and the remaining portion extends out from the proximal end 28 of the connecting segment 6. The remaining portion of the guide 40 is then inserted into the lumen of the body member 5 creating a slip-fit seal between the prostatic stent 3 and the connecting segment 6. Various other couplings are possible, so long as the distal terminating end 4 of the body member 5 and the proximal end 28 of the connecting segment 6 are releasably joined together. For example, in other embodiments, the guide 40 is releasably coupled to the prostatic stent 3 with sutures that can be removed in situ after the prostatic stent 3 is properly positioned.

After a prostatic procedure to treat an obstructed prostate, such as thermal therapy, the patient's prostate typically will still be slightly enlarged and it may bleed. To prevent bladder obstruction and to monitor the amount of urine production and prostate bleeding, a physician can insert the prostatic stent-catheter 1 into a patient's urethra until the proximal tip 2 is located within the bladder and the connecting segment 6 extends through the external sphincter as to allow constant drainage of fluids from the patient's bladder and through the patient's prostate. Once the physician has decided that the patient's bodily fluids no longer need to be monitored, constant fluid drainage from the patient's bladder is no longer necessary. To avoid the potential risk of bladder retention due to the slightly enlarged and recently treated prostate, however, the physician may wish to maintain the prostatic stent 3 within the prostatic section of the urethra until the prostate is completely resolved. The physician, realizing that patient's prostate could take several weeks to resolve and not wishing to inconvenience the patient, can remove the

09733752-120800

connecting segment 6 from the prostatic stent-catheter system 1 while leaving the prostatic stent 3 in place by simply pulling on the connecting segment 6.

And a<sup>3</sup> ~~The embodiment of the prostatic stent-catheter system 1 of FIGS. 1 and 2 further comprises a pushing device 12 and a handle 20. The pushing device 12 has a proximal end 36 and a distal end 34. The width of the pushing device 12 is sized to fit within the lumens of the prostatic stent 3 and the connecting segment 6, while the length of the pushing device 12 is sized so that the proximal end 36 can contact the proximal tip 2 of the prostatic stent 3 while the distal end 34 extends beyond the distal end 30 of the releasably connected connecting segment 6. Therefore, the physician performing the procedure can use the pushing device 12 to contact the proximal tip 2 of the prostatic stent 3 once the prostatic stent-catheter system 1 is already inserted into the patient's body. The pushing device 12 can be made from any material that is flexible enough to conform to the patient's anatomy, but also rigid enough to extend the proximal tip 2 away from the body member 5. Materials such as stainless steel or polycarbonate meet these criteria. The pushing device 12 can be either straight as shown in FIG. 7 or curved as shown in FIG. 8, to aid in the insertion and placement of the prostatic stent 3 within the prostatic section of the urethra. Extending through the entire pushing device 12 is a lumen capable of receiving a guide wire. At the proximal end 36 of the pushing device 12 is a flange 32 used to connect the proximal tip 2 to the pushing device 12. The flange 32 also prevents premature separation of the pushing device 12 from the proximal tip 2. The flange 32 is best illustrated in FIG. 9. The other end of the pushing device, the distal end 34, is attached to a mechanism 24 located within the handle 20. The mechanism 24 is slidably movable in the proximal and distal directions. Because the mechanism 24 is attached to the pushing device 12, the position of the mechanism 24 determines the position of the pushing device 12 within the prostatic stent-catheter system 1. The handle 20 is attached to the distal end 30 of the connecting segment and remains outside of the patient's body. Therefore, a physician has access to the position of the pushing device 12 at all times during a procedure. Besides the mechanism 24, the handle 20 also includes at least one opening 22 for drainage of fluids from the prostatic stent-catheter system 1.~~

09733752-120800

The embodiment of the prostatic stent **3** of FIGS. 1 and 2 includes a series of openings **10, 14a – 14d** in communication with the lumen of the body member **5**, and a series of protuberances **16a – 16e**. These features are most clearly illustrated in FIGS. 10-12. The series of openings **10, 14a-14d** and/or the series of protuberances **16a-16e** on the body member **5** decrease the likelihood of migration of the prostatic stent **3**. The protuberances may be parallel to each other or may be progressively angled to further decrease migration. In the disclosed embodiment, the series of protuberances **16a – 16e** have a serpentine pattern, however other possible patterns such as circular or spiral are possible. When the prostatic stent **3** is properly positioned, the series of protuberances **16a-16e** are in contact with the patient's prostate. Consequently, the series of protuberances **16a – 16e** create a source of friction between the prostatic stent **3** and the prostate which decreases movement of the prostatic stent **3**. The series of openings **10, 14a-14d** in the body member **5** also create friction between the patient's prostate and the prostatic stent **3**. The series of openings **10, 14a- 14d** further allow bodily fluids such as urine or blood to enter into the body member **5** of the prostatic stent **3** while permitting prostate tissue to extend into the prostatic stent **3** to aid in securing the prostatic stent **3** from migrating. To further prevent migration, the distal terminating end **4** may be belled outward to a diameter larger than the body member **5** but essentially equal to the connecting segment **6**. FIG. 12 is a cross sectional view of the prostatic stent **3**. In this drawing a proximal ledge **15** and a distal ledge **17** are noticeable in the internal prostatic stent **3** profile. The proximal ledge **15** is designed to receive the flange **32** of the pushing device **12** (shown in FIG. 9). The proximal ledge **15** provides a contact surface for the flange **32** to push against when the pushing device **12** is proximally extended. The distal ledge **17** is designed to receive the guide **40** (shown in FIG. 2). The distal ledge **17** provides a contact surface for the guide **40** to rest against while the prostatic stent **3** and the connecting segment **6** are coupled together.

As previously discussed, the prostatic stent **3** as illustrated in FIGS. 1 and 2 includes a retaining member **8** with at least two distinct states. The retaining member **8** is biased in the second state. The physician can change the retaining member's **8** configuration to the collapsed or first state by either applying pressure with his or her fingers to the retaining arms **13a – 13b** to extend the proximal tip **2** in the proximal direction and thus collapse the retaining member **8** or

09733752-120800

by proximally extending the pushing device **12** within the lumen of the prostatic stent-catheter system **1** to extend the proximal tip **2** and thereby collapse the retaining member **8**. In the latter case, the physician can control the process from outside of a patient's body by placing the mechanism **24** into a first position causing the extension of the pushing device **12**. This process is schematically illustrated in FIG. 13. Similarly, the retaining member **8** can be returned to the second state by either removing the pressure on the retaining member **8** or retracting the pushing device **12** within the prostatic stent-catheter system **1**. FIG. 14 shows the expansion of the retaining member **8** as a result of placing the mechanism **24** in a second position. To detach the pushing device **12** from the prostatic stent **3**, the mechanism **24** is placed into a third position, shown in FIG. 15.

Another embodiment of a prostatic stent-catheter system **100** is illustrated in FIG. 16. The prostatic stent-catheter system **100** comprises a prostatic stent **300** and a connecting segment **600**. The prostatic stent **300** includes a large pore mesh design **350**, a proximal end **370**, a distal end **340**, and a lumen extending between the proximal end **370** and the distal end **340**. An enlarged view of the large pore mesh design **350** is illustrated in FIG. 17. The large pore mesh **350** is fabricated from any self-expanding, biocompatible material such as nylon, polyglycolic acid, stainless steel or nickel-titanium based alloys. The large pore mesh **350** is produced by weaving, braiding, or heat bonding strands of the selected self-expanding, biocompatible materials together or by slotting or pattern cutting by laser and/or conventional machining a hollow tube of the selected material. The large pore mesh **350** may be coated with a thin polymeric layer to prevent trauma to the patient's urethra during insertion. Each pore **360** in the large pore mesh is an opening for fluids to drain into the lumen of the prostatic stent **300**. Because the prostatic stent **300** includes many pores, the possibility of all of the pores **360** becoming blocked by blood clots so as to inhibit drainage is small. The prostatic stent **300** is sized to fit within the prostatic section of the urethra. When properly positioned the proximal end **370** is located distal to the bladder while the distal end **340** terminates proximal to the external sphincter. In the disclosed embodiment, the prostatic stent **300** has a circular cross section. The shape of the cross section need not be circular. In other embodiments, a prostatic stent including a large pore mesh can have other cross sectional shapes such as a triangle or oval.

09733752-120800

In still yet other embodiments, the shape of a prostatic stent could differ from the disclosed embodiment by having a non-constant cross sectional shape such as hourglass or funnel shapes.

The prostatic stent-catheter system **100** of the embodiment illustrated in FIG. 16 further includes a guide **640** for coupling the prostatic stent **300** to the connecting segment **600**, a handle **200** including an activation mechanism **240** and openings for fluid drainage **260**, and a pushing device **120**. The pushing device has a bullet-shaped proximal end **122**. The bullet-shaped proximal end **122** is capable of capturing and collapsing the proximal end **370** of the prostatic stent **300**. The opposite end of the pushing device is attached to the activation mechanism **240** in the handle **200**. FIG. 18 illustrates the prostatic stent-catheter system **100** in a release configuration. The physician performing the procedure can achieve the release configuration by extending the pushing device **120** so that the bullet-shaped proximal end **122** releases the proximal end **370** of the prostatic stent **300**. The physician can then remove the connecting segment **600** from the prostatic stent-catheter system **100** by decoupling the connecting segment **600** from the prostatic stent **300**, and removing the connecting segment **600**, the handle **200**, and pushing device **120** from the patient's urethra.

The prostatic stent-catheter system **100** illustrated in FIG. 16 is placed into the patient's body, used in the patient's body, and removed from the patient's body in the same way that the other embodiments of prostatic stent-catheter systems described herein are placed, used, and removed.

The prostatic stent-catheter system **1** in FIGS. 19-25 is of the embodiment illustrated in FIGS. 1 and 2. In this embodiment, the prostatic stent **3** further comprises a retaining member **8** as previously described. In FIG. 19, the prostatic stent **3** in this invention is in its biased or natural state. The prostatic stent-catheter system **1** in FIGS. 19-25 further includes at least one suture **42**. In another embodiment, the suture **42** can be replaced with any tubular structure that is thin enough to pass through the external sphincter **54** without negatively impacting the operation of the external sphincter **54** such as a long membrane. The suture **42** or tubular structure can be useful when removing the prostatic stent **3** from the prostatic section of the urethra at some point after the prostate has resolved. To attach the suture **42** to the prostatic stent

09733752-120800

3 one end of the suture 42 is threaded through the distal terminating end 4 of the prostatic stent 3. The suture 42 is intended to run parallel to the prostatic stent 3 and connecting segment 6 walls along the lumen to reduce the likelihood of catching and holding blood clots. The other end of the suture 42 can be attached or connected to a retaining device 44. The retaining device 44 serves as a recovery means if the prostatic stent 3 proximally migrates. The retaining device 44 is slidably adjustable along the entire length of the suture 42, thereby allowing the physician to be able to position the retaining device 44 either within or external to the meatus 60. In the disclosed embodiment, the retaining device 44 is located external to the meatus 60 to permit erections. The retaining device 44 in FIGS. 19-25 is a bead. Various other embodiments of retaining devices are possible. Some of the other possible embodiments of retaining devices are illustrated in FIGS. 26-28.

Before a physician can insert the prostatic stent-catheter system 1 including a retaining member 8, the retaining member 8 must be collapsed. FIG. 20 shows a prostatic stent-catheter system 1 of a disclosed embodiment in an insertion or collapsed configuration. FIGS. 21-23 illustrate a method of inserting and placing a prostatic stent-catheter system 1. The remaining drawings, FIGS. 24-25 depict the decoupling of the prostatic stent 3 and the connecting segment 6 and the subsequent removal of the connecting segment 6 from a patient's urethra.

FIG. 21 shows an illustration of both the prostatic stent-catheter system 1 in the insertion configuration (i.e., collapsed retaining member), and a male urinary system 70. The male urinary system 70 including a urethra 58, an external sphincter 54, an opening to the external sphincter 56, a prostate 53, a prostatic section of the urethra 52, and a bladder 50. The point of insertion of the prostatic stent-catheter system 1 is the meatus 60.

To position the prostatic stent-catheter system 1 within a patient to relieve bladder outlet obstruction and to monitor a patient's bodily fluid excretions (post thermal prostate therapy, for example), a physician inserts the prostatic stent-catheter system 1 into a patient's urethra 58 through the meatus 60. This procedure is schematically illustrated in FIG 22. The prostatic stent-catheter system 1 is advanced through the urethra until the prostatic stent 3 is substantially

09733752 120800

within the prostatic section of the urethra 52 with the retaining member 8 residing in the bladder 50. The physician can confirm proper placement of the prostatic stent-catheter system 1 by observing urine flowing through the connecting segment 6. FIG. 23 illustrates schematically the proper placement of a prostatic stent-catheter system 1.

*As a 4)* ~~The prostatic stent-catheter system 1 remains inside the male urinary system 70 until a decrease in prostate bleeding is observed and a physician decides that it is no longer necessary to monitor a patient's bodily fluid excretions. Even though a patient's bodily fluid excretions no longer require monitoring, the patient's prostate 53 may still be obstructed. To prevent bladder outlet obstruction and to promote prostate 53 recovery, a physician may decide to leave the prostatic stent 3 in position, and to remove only the connecting segment 6 portion of the prostatic stent-catheter system 1. To remove the connecting segment 6, the physician first decouples the prostatic stent 3 and connecting segment 6 by pulling on the connecting segment 6 (FIG. 24). The physician is then able to withdraw the connecting segment 6 from the urethra 58 (FIG. 25). Once the connecting segment 6 portion of the prostatic stent-catheter system 1 is removed, the patient's external sphincter opening 56 contracts, allowing the external sphincter to operate normally and thus allowing the patient to control all bladder functions even though the prostatic stent 3 remains in place. The suture 42 attached to the prostatic stent 3 extends from the distal terminating end 4 through the urethra 58 and terminates just outside the meatus 60. The suture 42 is thin enough to pass through the contracted external sphincter opening 56 without negatively impacting the operation of the external sphincter or therefore the patient's bladder control. The removal of a prostatic stent 3 may be performed separately at some later time, by either pulling on the suture 42 or through endoscopic means.~~

Variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill in the art without departing from the spirit and the scope of the invention. The invention is not to be limited by the preceding illustrative description.

What is claimed is:

09733752-120800